

Application No. 10/706,738
Reply to Office Action of June 26, 2009

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REMARKS

Applicants note with appreciation the detail and thoroughness of the examination embodied in Paper No. 20090616. This amendment is submitted to be fully responsive thereto.

With entry of this amendment claims 1 and 20 are currently amended to recite that the Z is a six amino acid chain of arginine. These amendments are fully supported by the specification as filed *inter alia* page 11, lines 7-14. As such no new matter is introduced by way of amendment.

Currently, claims 8-16, 19, 20, 22, 24, 26, 27, and 30 are pending in the current application.

Claims 8, 10-15, 20, 22, 26, and 27 stand rejected under 35 U.S.C. §102(b) as being anticipated by Mahato et al. (U.S. Patent No. 6,875,611).

Claims 8, 10-15, 20, 22, 26, 27, and 30 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mahato et al. (U.S. Patent No. 6,875,611).

Claims 8, 10-15, 19, 20, 22, 24, 26, 27, and 30 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Niedzinski et al. (Lipids 35(7): 721-727, 2000), Keener et al. (U.S. Patent No. 6,627,197), Gebeyehu et al. (U.S. Patent No. 6,075,012), and Mahato et al. (U.S. Patent No. 6,875,611).

Claim 16 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Niedzinski et al. (Lipids 35(7): 721-727, 2000), Keener et al. (U.S. Patent No. 6,627,197), Mahato et al. (U.S. Patent No. 6,875,611), Gebeyehu et al. (U.S. Patent No. 6,075,012) and further in view of Perrie et al. (Journal Liposome Research 12 (1 & 2): 185-197, 2002).

Claim 16 stands rejected under the 35 U.S.C. §103(a) as being unpatentable over Niedzinski et al. (Lipids 35(7): 721-727, 2000), Keener et al. (U.S. Patent No. 6,627,197),

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Mahato et al. (U.S. Patent No. 6,875,611), Gebeyehu et al. (U.S. Patent No. 6,075,012) and further in view of Kitadai et al. (British Journal of Cancer 81(14): 647-653, 1999).

**Remarks Directed to the Rejection of Claims 8,
10-15, 20, 22, 26, and 27 as Anticipated by Mahato**

Reconsideration and withdrawal of the rejection of claims 8, 10-15, 20, 22, 26, and 27 as anticipated by Mahato is respectfully requested in view of the current amendments to claims 1 and 20 to recite that the Z is a six amino acid chain of arginine.

In *Richardson v. Suzuki Motor Co. Ltd.*, 868 F.2d 1226 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim." For anticipation to be found "the identical invention must be shown in as complete detail as is contained in the claim."

Mahato fails to teach or suggest the claimed composition wherein the Z moiety is a six amino acid chain of arginine. As all elements of claims 1 and 20 are neither taught nor suggested by Mahato, reconsideration and withdrawal of the rejections as to claims 1 and 20 are respectfully requested. As claims 10-15 depend from claim 1 which is believed to be in allowable form and directed to patentable subject matter, claims 10-15 are similarly submitted to be patentable over Mahato. As claims 22, 26, and 27 each depend from claim 20 which is believed to be an allowable form and directed to patentable subject matter, claims 22, 26, and 27 are similarly believed to be allowable over Mahato.

In light of the foregoing amendments and remarks, reconsideration and withdrawal of the rejections of claims 8, 10-15, 20, 22, 26, and 27 as anticipated over Mahato is respectfully requested. Additional bases of patentability exist and Applicants reserve the right to present these in the course of prosecution as necessary.

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Remarks Directed to the Rejections of Claims 8, 10-15, 20, 22, 26, 27, and 30 under 35 U.S.C. §103(a) as Unpatentable over Mahato

Reconsideration and withdrawal of the rejections of claims 8, 10-15, 20, 22, 26, 27, and 30 are respectfully requested in view of the amendments to claims 8 and 20 to recite that the Z moiety is a six amino acid chain of arginine. In view of these amendments the prior art combinations are respectfully submitted to be overcome.

The basis of the rejection is that Mahato taught all elements of the pending claims, thus, rendering claims 8, 10-15, 20, 22, 26 and 27 obvious thereover. Applicant incorporates by reference the remarks *supra* that Mahato fails to teach or suggest a molecule with a Z moiety that is a six amino acid side chain of arginine. To establish *prima facie* obviousness of a claimed invention, all claimed limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Furthermore, if an independent claim is non-obvious under 35 U.S.C. §103, then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). As all elements of claims 8 and 20 as currently amended are neither taught nor suggested by Mahato, it is submitted that claims 8 and 20 are non-obvious thereover. As claims 10-15 and 22, 26, 27, and 30 each depend from allowable base claims, these claims are similarly submitted to be non-obvious over Mahato.

In view of the foregoing amendments and remarks, reconsideration and withdrawal of the rejection of claims 8, 10-15, 20, 22, 26, 27, and 30 as unpatentable over Mahato is requested.

Remarks Directed to the Rejection of Claims 8, 10-15, 19, 20, 22, 24, 26, 27, and 30 under 35 U.S.C. §103(a) as Unpatentable over Niedzinski, Keener, Gebeyehu, and Mahato

Reconsideration and withdrawal of the rejections of claims 8, 10-15, 19, 20, 22, 24, 26, 27, and 30 as unpatentable over Niedzinski in view of Keener, Gebeyehu, and Mahato are respectfully requested in view of the current amendments to claims 8 and 20.

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Applicant incorporates by reference the remarks *supra* that Mahato fails to teach or suggest any cholic acid binding complex with a Z moiety that is a six amino acid chain of arginine.

Niedzinski is cited as teaching "Cholic acid conjugates comprising a substituted alkyl polyamine DNA binding domain and their use to protect DNA from degradation in the gastric system." (Paper No. 20090616, page 5.) Niedzinski is further recognized as failing to teach the specific cholesterol derivatives recited in claim 8 and claim 20, *Id.*, and as failing to teach a DNA binding domain comprising a peptide. *Id.* at 5-6.

Keener, Mahato and Gebeyehu are cited as supporting Niedzinski's deficiency to teach cholesterol derivatives as in claims 8 and 20. *Id.* at 5-6. Keener is further cited as teaching bile acids to "aid in the cellular entry of a conjugated peptide" such as proricin. *Id.* at 5. Mahato is cited as teaching ketianic lipids conjugated to a ketianic protamine peptide. *Id.* Gebeyehu is cited as teaching "that substituted alkyl polyamines and polycationic nucleic acid binding peptides such as protamines and histones were exchangeable equivalent nucleic acid binding domains." *Id.* at 7. The outstanding office action concludes:

It would also have been obvious to one of ordinary skill in the art at the time of the invention to substitute a nucleic acid binding peptide, such as that taught by Mahato or Gebeyehu, for the nucleic acid binding polyamine of Niedzinski because these nucleic acid binding moieties were recognized in the art as equivalents in view of the teachings of Gebeyehu, i.e. polyamines are equivalents of polycationic nucleic acid binding peptides. (Paper No. 20090616, page 9.)

Niedzinski, Keener, Gebeyehu, and Mahato alone or in combination fail to teach or suggest that a Z moiety can be a six amino acid chain of arginine. The outstanding Office Action depends on a claim of art recognized equivalence between polyamines and other polycationic

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nucleic acid binding peptides. (Paper No. 20090616, page 9.) A polyarginine of six amino acids is, however, neither the art-recognized equivalent of nor performs equivalently to any other polyarginine, protamine, histone, or polylysine on the basis that polyarginine tailed compounds currently claimed do not have a predictable cell permeability as part of a complex with DNA across the range of 1 to 50 residues (Z). In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on Applicant's disclosure or the mere fact that components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590 (C.C.P.A. 1958). A demonstration that a claimed element is not an equivalent effectively rebuts an assertion of art-recognized equivalence.

The outstanding rejection also fails to satisfy the test for *prima facie* obviousness of chemical matter used by the CAFC since *KSR*. The CAFC has interpreted *KSR* to require an explicit showing of where the prior art suggested making the specific modifications necessary to achieve the claimed invention. As was recently articulated by the CAFC, for a case of *prima facie* obviousness to be found for chemical matter, "[i]n addition to structural similarity between the compounds, a *prima facie* case of obviousness also requires a showing of 'adequate support in the prior art' for the change in structure." *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 83 USPQ2d 1169, 1174 (Fed. Cir. 2007). The court further made expressly clear that "in order to find a *prima facie* case of unpatentability in such instances, a showing that the 'prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention' was also required." *Id.* The court clarified that this test for chemical compounds is "consistent with the principles enunciated in *KSR*." *Id.* (citing *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007)). The CAFC still more recently articulated this standard *The Proctor and*

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Gamble Co. v. Teva Pharmaceuticals, Inc., CAFC 2008-1404 (decided May 13, 2009). The holdings of the CAFC make clear that for chemical matter, *prima facie* obviousness requires more than a mere showing that independent elements of the claimed compound were known in the prior art. The particular modifications and locations of those modifications must have been suggested.

Niedzinski fails to teach DNA binding domains comprising peptides. Keener teaches merely polylysine. Mahato teaches merely protamines. Gebeyehu teaches merely substituted alkyl polyamines that are not representative of amino acid side chains. As such, none of the cited prior art teaches or suggests a six amino side chain of arginine as either an art recognized equivalent or nor expressly suggested by any of the cited prior art. Moreover, taking the assertion in Paper No. 20090616 to its logical conclusion, if protamines, histones and all peptides are art recognized equivalents, then all proteins and proteinaceous type side chains must then similarly be art recognized equivalents as DNA binding domains. A person of ordinary skill in the art clearly recognizes that this is not the case. The specific structure of any proteinaceous chain will have vastly different characteristics in its ability to interact with and bind to DNA. As none of the cited prior art teaches or suggests the claimed six amino acid chain of arginine as the Z moiety in claims 8 and 20, Applicants submit that the outstanding rejections are overcome.

With respect to the rejection of claim 16 over Niedzinski, Keener, Gebeyehu, Mahato and either Perrie, or Kitadai, Applicants submit that neither Perrie nor Kitadai correct the aforementioned deficiencies in the other cited prior art. Moreover, as claim 16 is dependent from claim 8 which Applicants submit is directed to patentable subject matter, claim 16 is similarly allowable as dependent from an allowable base claim.

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In view of the foregoing amendments and remarks, Applicants submit that all claims are non-obvious over the cited prior art combinations. Reconsideration and withdrawal of the rejections of all claims under 35 U.S.C. §103(a) is respectfully requested.

Summary

Claims 8-16, 19, 20, 22, 24, 26, 27, and 30 are the pending claims in this application. Each claim is believed to be in proper form and directed to allowable and patentable subject matter. Reconsideration and allowance of the claims is requested. The Examiner is kindly requested to contact the undersigned attorney in charge of this application in the event that issues remain after consideration of this amendment.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1180.

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Respectfully submitted,

By 

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